MAY 2 2 2001

K003105

BioSphere Medical
1050 Hingham St.
Rockland, MA 02370

510K Summary of
Safety and Effectiveness

1. Sponsor Name
   Sponsor/Manufacturer
   BioSphere Medical
   1050 Hingham St.
   Rockland, MA 02370
   Telephone: 781 681 7900
   Contact Individual: John Bonasera

2. Device Name:
   BioSphere Medical Infusion Catheter

3. Identification of Predicate or Legally Marketed Device
   The BioSphere Medical Infusion Catheter is substantially equivalent in intended use and/or function to the following predicate devices: the Boston Scientific Renegade Hi-Flo Microcatheter and the Cordis Endovascular Prowler Plus Infusion Catheter.

4. Device Description
   The BioSphere Medical Infusion Catheter is designed and intended for use in the delivery of fluids into the body vasculature, addressing a number of medical conditions and providing functions which include: thrombolytic therapy, chemotherapy, embolotherapy and selective angiography. The design and materials used in the construction of the BioSphere Medical Infusion Catheter are widely established in the medical device industry.

   The BioSphere Medical Infusion Catheter may be introduced into body over a guide wire and/or through another catheter. Once in position, the infusion of agents can begin. To inject or infuse agents, an infusion line or syringe must be attached to the luer-lock using standard procedures. Fluids should be injected or infused using the manufacturer's instructions for dosage and duration.

5. Intended Use
   Infusion of various diagnostic, embolic and therapeutic agents into the vascular systems (neuro, peripheral, coronary), for guidewire exchange/support, and for superselective angiography of the peripheral and coronary cardiovasculatures.

6. Comparison of Technological Characteristics

The design of the BioSphere Medical Infusion Catheter and the materials used in its construction are similar to the predicate catheters. All have a flexible shaft which is reinforced with braided material to increase pushability and kink resistance
All of the catheters have a progressively softer shaft as one moves from the proximal to distal ends. The proximal end of each has a hub with a locking luer. All of the catheters have an outer coating to facilitate movement through the body's vasculature.

The BioSphere Medical Infusion Catheter is available in a variety of lengths from 75 cm to 175 cm. The predicate Cordis Endovascular Prowler Plus Infusion Catheter and Boston Scientific Renegade Hi-Flo Microcatheter are also available in a variety of lengths.

7 Performance Testing

The BioSphere Medical Infusion Catheter has been tested in accordance with ISO 10555-1:1995, "Sterile, Single-Use Intravascular Catheters".

8 Warnings, Precautions and Complications

Warnings:

The BioSphere Medical Infusion Catheter is intended for one procedure only. Do not resterilize and/or reuse the device. Reuse and/or resterilization may lead to device failure which could result in patient injury, illness or death. Reuse or resterilization may create a risk of contamination of the device and/ or cause patient infection, cross-infection, or transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

Infusion pressure with this catheter should not exceed 300 psi. Pressure in excess of this maximum may result in catheter rupture or device failure, possibly resulting in patient or user injury. If the flow of material through the catheter becomes restricted, do not attempt to clear the catheter lumen by infusion. Identify and resolve the cause of the blockage or replace the catheter with a new catheter before resuming infusion.

Precautions:

- This device should be used only by physicians thoroughly trained in percutaneous, intravascular techniques and procedures in relevant areas of the anatomy.
- This device is intended for single use only.
- The BioSphere Medical Infusion Catheter is supplied sterile. Verify that the package integrity has been maintained to assure the sterility of the device.

- Use the device prior to the "Expiration Date" noted on the package.
- Prior to a procedure, all equipment to be used for the procedure should be carefully examined to verify proper function and integrity.
- Inspect the infusion catheter prior to use for any bends or kinks. Any catheter damage may decrease the desired performance characteristics.
- When the infusion catheter is in the body, it should be manipulated only under fluoroscopy. Do not attempt to move the catheter without observing the resultant tip response.
- Never advance or withdraw an intravascular device against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the catheter or guidewire against resistance may result in separation of the catheter or guidewire tip, damage to the catheter, or vessel perforation.
- Extensive guidewire manipulation during lengthy procedures and the use of embolic agents may require the exchange of new catheters in place of the used catheters.
- Because the infusion catheter may be advanced into narrow subselective vasculature, repeatedly assure that the catheter has not been advanced so far as to interfere with its removal.
- Excessive tightening of a hemostatic valve onto the catheter shaft may result in damage to the catheter.
- The BioSphere Medical Infusion Catheter is able to be used with steerable guidewires that are up to .018 inches in outer diameter.

Complications:

- Possible complications include, but are not limited to the following:
- Air embolism
- Hematoma at the puncture site
- Infection
- Perforation of vessel wall
- Distal embolization

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 2 2001

Mr. John D. Bonasera
Director of Regulatory Affairs and Quality Assurance
BioSphere Medical™
1050 Hingham Street
Rockland, MA 02370

Re: K003105
Trade Name: BioSphere Medical Infusion Catheter
Regulation Number: 870.1200
Regulatory Class: II (two)
Product Code: 74 DQO
Dated: April 27, 2001
Received: April 30, 2001

Dear Mr. Bonasera:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003105

Device Name: BioSphere Medical Infusion Catheter

Indications For Use:

Infusion of various diagnostic, embolic and therapeutic agents into the vascular systems (neuro, peripheral, coronary), for guidewire exchange/support, and for superselective angiography of the peripheral and coronary cardiovasculatures.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003105